

APPLICATION FOR PATENT

5 Inventor(s): Gil Vardi and Eric Williams

Title: DUAL GUIDEWIRE EXCHANGE CATHETER SYSTEM

10

This application claims the benefit of U.S. Provisional Patent Application Serial Number 60/413,552, filed September 26, 2002, and is also a continuation-in-part of co-pending U.S. Patent Application Serial Number 09/860,744, filed May 18, 2001, both of which are incorporated by reference herein in their
15 entireties.

FIELD AND BACKGROUND OF THE INVENTION

The present invention relates generally to the field of medical catheters, and
20 more specifically to a catheter used to deliver medical stents. In one aspect, the invention further relates to methods for deploying stents in vessels such that a side opening in the stent wall is aligned with an ostium of a branch vessel. In other aspects, the invention is related to the management of guidewires over which such catheters are introduced.

25 A stent is a type of endoprosthesis device, typically intraluminally placed or implanted within a vein, artery, or other tubular body organ for treating an occlusion, stenosis, aneurysm, collapse, dissection, or weakened, diseased, or abnormally dilated vessel or vessel wall, by expanding the vessel or by reinforcing the vessel wall. In particular, stents are quite commonly implanted into the coronary, cardiac, pulmonary,
30 neurovascular, peripheral vascular, renal, gastrointestinal and reproductive systems, and have been successfully implanted in the urinary tract, the bile duct, the esophagus, the tracheo-bronchial tree and the brain, in order to reinforce these body organs. Two important current widespread applications for stents are for improving angioplasty results by preventing elastic recoil and remodeling of the vessel wall and for treating
35 dissections in blood vessel walls caused by balloon angioplasty of coronary arteries as well as peripheral arteries. Conventional stents have been used for treating more complex vascular problems, such as lesions at or near bifurcation points in the vascular system, where a secondary artery branches out of a larger, main artery, with

limited success rates, as described by Chevalier, B., et al., in the American Journal of Cardiology, 82: 943-949, 1998; Yamashita, T., et al., in the Journal of American Coll ge of Cardiology, 35: 1145-1151, 2000; and Satler, S., et al., in Catheterization and Cardiovascular Interventions, 50: 411-412, 2000.

5 Conventional stent designs typically feature a straight tubular, single type cellular structure, configuration, or pattern which is repetitive through translation along the longitudinal axis, and sometimes also along the radial axis of the stent. The repeating structure, configuration, or pattern has strut and connecting members that can impede blood flow at bifurcations. Furthermore, the configuration of struts and
10 connecting members may obstruct the use of post-operative devices to treat a branch vessel in the region of a vessel bifurcation. For example, a physician may be unable to insert a branch stent through the ostium of a branch vessel of a vessel bifurcation in cases where treatment of the main vessel is suboptimal as a result of displacing diseased tissue (plaque shifting or 'snow plowing'), occlusion, vessel spasm,
15 dissection with or without intimal flaps, thrombosis, embolism, and/or other vascular diseases. Accordingly, the use of regular stents to treat diseased vessels at or near a vessel bifurcation may create a risk of compromising the degree of patency of the main vessel, branch vessels, and/or the bifurcation point.

Non-conventional stents, such as a stent with a side opening for branch vessel
20 access, or double stenting systems can be used to overcome some of the above limitations. Delivery of such non-conventional stents often requires the use of non-conventional catheters. For example, catheters with two lumens for guidewires – a main guidewire lumen and a branch guidewire lumen – are used to deliver stents with side branch access. Examples of such catheters are described, for example, in
25 co-pending U.S. Application Serial Number 09/663,111, filed September 15, 2000 and co-pending U.S. Application Serial Number 09/455,299, filed December 6, 1999, both of which are incorporated herein by reference in their entireties.

However, the use of such non-conventional stents and catheters produces additional challenges, resulting from the use of more than one guidewire. After a
30 guidewire is appropriately positioned within the patient body, a trailing end portion of the guidewire typically extends out of the patient body from the point of entry. It has been found that the trailing end portion of the guidewire outside the patient body can be rather difficult to manage and can interfere with the efficiency of the medical

procedure performance. This is especially true when more than one guidewire is being used during a medical procedure. In such a case, the medical practitioner performing the procedure may confuse the trailing end portions of the guidewires protruding from the patient body with one another. Furthermore, long wires are
5 difficult to manage and often require more than one individual for proper manipulation. This problem is exacerbated when more than one long wire is used.

When using multiple wires to introduce a catheter system, one condition that may occur is known as "wire crossing." In such cases, the guidewires over which the catheter system is advanced intertwine within the guide catheter and vasculature.
10 This condition may prevent the successful delivery of the catheter system by impeding its travel and subsequently, the alignment of the stent's side opening with the ostium of the branch vessel.

There is thus a widely recognized need for, and it would be highly advantageous to have, a dual guidewire catheter system that avoids the above
15 limitations.

SUMMARY OF THE INVENTION

According to one aspect of the present invention, there is provided a catheter system for positioning a stent at a vessel bifurcation. The catheter system includes a catheter having a channel with a main guidewire lumen extending proximally from a distal end of the catheter to a main exit port located at a first distance from the distal end, wherein the main guidewire lumen is configured to receive a main vessel guidewire therethrough, a branch guidewire enclosure positioned alongside the channel and extending proximally from the side opening of the stent to a branch exit port located at a second distance from the distal end of the catheter system, wherein the branch guidewire lumen is configured to receive a branch vessel guidewire therethrough, and a stent having a lumen and a side opening in a wall thereof, the stent positioned on a distal portion of the channel, and wherein a distal portion of the branch guidewire enclosure is positioned through the lumen and exiting at the side opening, wherein at least one of the distances is less than a distance from the distal end of the catheter system to a proximal end of the catheter system and greater than a distance from the distal end of the catheter system to the proximal end of the stent.

According to another aspect of the present invention, there is provided a catheter having a proximal tube portion, a distal portion having a first lumen and a second lumen, wherein the first lumen is configured to receive a first guidewire and the second lumen is configured to receive a second guidewire, and a bond portion connecting the proximal portion with the distal portion, wherein the bond portion includes a three-way bond.

According to another aspect of the present invention, there is provided a method of inserting a catheter system into a bifurcated body lumen having a main vessel and a branch vessel. The method includes providing a catheter having a channel with a main guidewire lumen configured to receive a main vessel guidewire therethrough and a branch guidewire lumen positioned alongside the channel configured to receive a branch vessel guidewire therethrough, providing a first guidewire having a proximal end and a distal end and a length of less than 50 centimeters, and a second guidewire having a proximal end and a distal end and a length of less than 50 centimeters, inserting the first guidewire into a first vessel, inserting the second guidewire into the first vessel, inserting the proximal end of the first guidewire into the main guidewire lumen of the catheter, inserting a proximal end of the second guidewire into the branch guidewire lumen of the catheter, advancing the catheter over the first guidewire and the second guidewire into the body lumen until a vicinity of the bifurcation, retracting the second guidewire until the distal end of the second guidewire is in the vicinity of the bifurcation, advancing the second guidewire into the branch vessel, and advancing the catheter over the first and second guidewires.

According to further features in preferred embodiments of the invention described below, the catheter system includes a balloon disposed on the channel and through the lumen of said stent, the balloon being for expansion of the stent, and the channel includes an inflation portion for inflating the balloon.

According to still further features in preferred embodiments of the invention described below, the catheter system includes a bond portion connecting the main exit port and branch exit port to a proximal tube, the proximal tube extending proximally from the bond portion to the proximal end of the catheter system.

According to still further features in preferred embodiments of the invention described below, the first distance is between 10 and 50 centimeters, the second

distance is between 10 and 50 centimeters and the first distance is approximately equal to the second distance. Alternatively, the first distance is between 10 and 50 centimeters and the second distance is between 50 and 150 centimeters, and the branch guidewire enclosure extends proximally to the proximal end of said catheter. In one aspect, the branch guidewire enclosure is a side sheath.

According to still further features in preferred embodiments of the invention described below, the catheter system includes a main vessel guidewire and a branch vessel guidewire which are less than 50 centimeters in length.

According to still further features in preferred embodiments of the invention described below, the first and second lumens are attached along their entire lengths, or only at the bond portion. The bond portion is located at a predetermined distance from a proximal portion of the stent, wherein the distance is between 5 and 15 centimeters.

Unless otherwise defined, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this invention belongs. Although methods and materials similar or equivalent to those described herein can be used in the practice or testing of the present invention, suitable
5 methods and materials are described below. In case of conflict, the patent specification, including definitions, will control. In addition, the materials, methods, and examples are illustrative only and not intended to be limiting.

BRIEF DESCRIPTION OF THE DRAWINGS

10 The invention is herein described, by way of example only, with reference to the accompanying drawings. With specific reference now to the drawings in detail, it is stressed that the particulars shown are by way of example and for purposes of illustrative discussion of the preferred embodiments of the present invention only, and are presented in the cause of providing what is believed to be the most useful and
15 readily understood description of the principles and conceptual aspects of the invention. In this regard, no attempt is made to show structural details of the invention in more detail than is necessary for a fundamental understanding of the invention, the description taken with the drawings making apparent to those skilled in the art how the several forms of the invention may be embodied in practice.

20 In the drawings:

FIG. 1 is an elevational view of a dual guidewire exchange catheter system in accordance with a preferred embodiment of the present invention;

FIG. 2 is an illustration of the bond portion of the catheter of FIG. 1;

FIG. 3 is an elevational view of a region of the catheter of FIG. 1 distal to the
5 bond portion illustrated in FIG. 2;

FIG. 4 is a cross section illustration of the catheter in the region of FIG. 3;

FIGS. 5A-5G are illustrations of the steps of a method of inserting a catheter such as the one shown in FIG. 1 into a bifurcated body lumen and further deploying a stent therein; and

10 FIGS. 6A-6B are illustrations of the steps of an alternative method of inserting a catheter such as the one shown in FIG. 1 into a bifurcated body lumen.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

15 The present invention is of a dual guidewire exchange catheter system for delivery of a stent with a side opening, which can be delivered to a vessel bifurcation. Specifically, the present invention can be used to deliver a stent to a vessel bifurcation while controlling guidewire management.

The principles and operation of a dual guidewire exchange catheter according
20 to the present invention may be better understood with reference to the drawings and accompanying descriptions.

Before explaining at least one embodiment of the invention in detail, it is to be understood that the invention is not limited in its application to the details of construction and the arrangement of the components set forth in the following
25 description or illustrated in the drawings. The invention is capable of other embodiments or of being practiced or carried out in various ways. Also, it is to be understood that the phraseology and terminology employed herein is for the purpose of description and should not be regarded as limiting.

Reference is now made to FIG. 1, which is an elevational view of a dual
30 guidewire exchange catheter system 10 in accordance with a preferred embodiment of the present invention. Catheter system 10 has a distal end 12 and a proximal end 14. At proximal end 14, catheter system 10 includes a luer hub 16 with a strain relief portion 18. A hypotube 20 extends along most of the length of catheter system 10,

followed by an inflation tube 22 with a bond portion 24, and a distal shaft 26 positioned alongside inflation tube 22 in a region distal to bond portion 24. Inflation tube 22 leads into a balloon 28, while distal shaft 26 leads into a side sheath 30 positioned alongside balloon 28. According to one embodiment of the present invention, the length of catheter system 10 from proximal end 14 to distal end 12 is between 100 cm and 200 cm. In a preferred embodiment, the length of catheter system 10 from proximal end 14 to distal end 12 is approximately 140-150 cm.

In a preferred embodiment, luer hub 16 is comprised of a polymer material, such as polycarbonate, acrylic, or any other suitable material, and strain relief portion 18 is comprised of silicone. Strain relief portion 18 provides a transition between the relatively stiff luer hub 16 and the less stiff hypotube. As such, any suitable polymer with an intermediate stiffness may be used. In a preferred embodiment, coated hypotube 20 is comprised of a biocompatible metal, such as stainless steel, titanium, cobalt-chromium, or any other suitable material. In one embodiment, hypotube 20 is coated with a polymer such as polyethylene, Pebax, nylon or others. In one embodiment, hypotube 20 has a hollow interior, with an inner diameter of 0.01-0.02 inches and an outer diameter of 0.02-0.04 inches. In a preferred embodiment, hypotube 20 has an inner diameter of 0.012-0.019 inches and an outer diameter of 0.025-0.031 inches. Inflation tube 22 is sealed to and surrounds hypotube 20 at an intermediate point along the length of hypotube 20. In a preferred embodiment, inflation tube 22 is comprised of a mixture of Pebax (approximately 96%) and granite (approximately 4%), although in alternative embodiments it can be comprised of any suitable polymer or combination of materials. Bond portion 24 is attached to inflation tube 22 at a point distal to the proximal end of inflation tube 22. Details of bond portion 24 will be described hereinbelow with respect to FIG. 2.

Distal to bond portion 24, distal shaft 26 is positioned alongside inflation tube 22. Distal shaft 26 is comprised of a polymer or composite material. In a preferred embodiment, distal shaft 26 is comprised of Nylon 12 and Vestamid L2124. Many different attachment configurations for distal shaft 26 and inflation tube, leading into side sheath 30 and balloon 28, respectively, are envisioned. In one embodiment, distal shaft 26 is attached to inflation tube 22 but side sheath 30 is detached from balloon 28. In another embodiment, distal shaft 26 is attached to inflation tube 22 along its length, and side sheath 30 is at least partially attached to balloon 28. In yet another

embodiment, distal shaft 26 is only attached to inflation tube 22 at a specific point or points along its length, and is detached from inflation tube 22 at other portions. For example, distal shaft 26 can be attached to inflation tube 22 in the region of bond portion 24 and at a point just proximal to balloon 28. Alternatively, distal shaft 26 can be attached to inflation tube 22 only in the region of bond portion 24.

Reference is now made to FIG. 2, which is an illustration of bond portion 24 in greater detail. Bond portion 24 is a three-way bond, connecting one portion of tubing (inflation tube 22) on the proximal end of bond portion 24 and two portions of tubing (inflation tube 22 and a distal shaft 26) on the distal end of bond portion 24. As shown in FIG. 2, a bonding area 23 connects distal shaft 26 to inflation tube 22. In a preferred embodiment, the materials in the bond portion are nylon/Pebax and are thermally fused together to form the bond.

Reference is now made to FIG. 3, which is an elevational view of a region of catheter 10 which is distal to bond portion 24, having a stent 32 positioned on balloon 28. Stent 32 is a metallic mesh with a configuration of struts and connectors, which is positioned on balloon 28 in an unexpanded state, and which can be expanded once in place within a vessel so as to provide support to the walls of the vessel and allow for unobstructed flow of blood. Stent 32 can be any suitable stent, such as the ones described in, for example, co-pending U.S. Application Serial Number 09/600,348, filed July 14, 2000, co-pending U.S. Application Serial Number 09/963,114, filed September 24, 2001 and PCT International Application Serial Number IL02/00840, filed October 20, 2002, all of which are incorporated herein by reference in their entireties. Stent 32 further includes a side opening 34, through which side sheath 30 is positioned so as to allow side sheath 30 to be positionable in a vessel bifurcation. In an alternative embodiment, side sheath 30 is positioned at side opening 34 of stent 32 and does not protrude therethrough, but allows a guidewire placed therein to be positioned through side opening 34 and into a branch vessel. The relative lengths of tubing distal to bond portion 24 can be seen in FIG. 3. It should be readily apparent, however, that the lengths may vary. In one embodiment, the length of distal shaft 26 and inflation tube 22 from bond portion 24 until balloon 28 is 1-100 cm. In an exemplary preferred embodiment, the length of distal shaft 26 and inflation tube 22 from bond portion 24 until balloon 28 is approximately 30 cm. By distancing the balloon and stent from bond portion 24 (by around 10 cm or more), more flexibility in

rotation of the system is provided, facilitating rotational alignment of side opening 34 of stent 32 with the ostium of the branch vessel. Furthermore, stiffness in the area of the stent is reduced by not having extra bond material present in the general region of the stent.

5 Reference is now made to FIG. 4, which is a cross-section illustration of the region of catheter 10 shown in FIG. 3. Inflation tube 22 has a main guidewire lumen 35, wherein main guidewire lumen 35 has a smaller diameter than that of inflation tube 22. This configuration allows communication via a fluid communication zone 33 between inflation tube 22 and the inside of balloon 28, through which inflation fluid
10 may be provided to balloon 28, thus allowing balloon 28 to expand. Main guidewire lumen 35 extends from a main guidewire exit port 39 to distal end 12 of catheter system 10, exiting through a tip 37 of catheter 10. A main vessel guidewire 36 can be positioned within main guidewire lumen 35, wherein a distal portion of main vessel guidewire 36 is positionable within the main vessel. Since main guidewire exit port 39
15 is a relatively short distance from tip 37, a relatively short length of main guidewire 36 is needed, in a range of, for example, 3-35 cm, particularly as compared to an over-the-wire system, wherein the main guidewire lumen would extend along the entire length from tip 37 to the proximal end of a catheter. Similarly, distal shaft 26 includes a branch vessel guidewire lumen 40, which extends from a branch vessel
20 guidewire exit port 41 to the distal end of side sheath 30. A branch vessel guidewire 38 can be positioned within branch vessel guidewire lumen 40, wherein a distal portion of branch vessel guidewire 38 is positionable within a branch vessel. Since branch vessel guidewire exit port 41 is a relatively short distance from the distal end of side sheath 30, a relatively short length of branch vessel guidewire 38 is needed, in a
25 range of, for example, 3-35 cm, particularly as compared to a system wherein the branch vessel guidewire lumen would extend along the entire length from side sheath 30 to the proximal end of a catheter. Thus, catheter 10 has dual guidewire exchange capability, in that either main vessel guidewire 36 or branch vessel guidewire 38 or both may be relatively short in length, allowing for management of shorter wires
30 outside of the body. In an alternative embodiment, the locations of exit ports 39 and 41 are located apart from one another along the length of the system. This configuration would enable reduction of the profile of the overall system.

10

Suitable methods for advancing a dual guidewire exchange catheter system such as the one described hereinabove are described and illustrated in FIGS. 5A-5G and 6A-6B. Reference is made first to FIGS. 5A-5G, which are illustrations of the steps of inserting catheter system 10 into a bifurcated body lumen and expanding stent 32 therein, in accordance with a preferred embodiment of the present invention. FIGS. 5B-5F illustrate catheter system 10, to be deployed in a bifurcation 2, wherein a main vessel 3 is split into a main vessel continuation 4 and a branch vessel 5. As shown in FIG. 5A, both main vessel guidewire 36 and branch vessel guidewire 38 are initially placed in the main vessel 3, preferably extending into main vessel continuation 4. Optionally, a safety guidewire (not shown) can be inserted into the branch vessel for reference and for support of the branch vessel. As shown in FIG. 5B, catheter system 10 is then advanced over both vessel guidewires, with main vessel guidewire 36 being positioned through main guidewire lumen 35 of catheter system 10 and with branch vessel guidewire 38 being positioned through side sheath 30 and branch vessel guidewire lumen 40 of catheter system 10. It should be readily apparent that by using a system such as the one described above, shorter lengths of either or both vessel guidewires can be used, since only a relatively short amount of wire is needed outside of the body for threading into the system. This provides ease of maneuverability of wires outside of the body. Additionally, since the wires can more easily be manipulated, this can lead to greater control of the wires within the body, possibly reducing wire entanglement. As shown in FIG. 5C, branch vessel guidewire 38 is then retracted until its tip is opposite or proximal to the ostium of branch vessel 5. Subsequently, as shown in FIG. 5D, branch vessel guidewire 38 is advanced into branch vessel 5. If a safety wire is present, it is removed at this point. Next, as shown in FIG. 5E, catheter system 10 is advanced over both wires until stent 32 is in its optimal position with respect to the ostium of the bifurcation. Balloon 28 is then expanded by introducing fluid into balloon 28 via inflation tube 22, wherein the expansion of balloon 28 causes stent 32 to be deployed, as shown in FIG. 5F. Finally, as shown in FIG. 5G, catheter system 10 and guidewires 36 and 38 are removed, leaving only the expanded stent 32 in place.

In an alternative embodiment, both guidewires 36, 38 are initially placed in the branch vessel 5, and catheter system 10 is advanced over the two wires. In the alternative embodiment just described, main vessel guidewire 36 is retracted and

subsequently advanced through main vessel 3 and into main vessel continuation 4. By initially positioning both guidewires 36 and 38 in the same vessel, crossover and entanglement of the wires may be further minimized.

Reference is now made to FIGS. 6A and 6B, which are illustrations of the steps of an alternative method of advancing a dual lumen dual side exchange system such as the one described hereinabove. As shown in FIG. 6A, initially main vessel guidewire 36 is positioned within main vessel 3 and into main vessel continuation 4, and branch vessel guidewire 38 is positioned within main vessel 3 and into branch vessel continuation 5. Following initial placement of wires 36 and 38, catheter system 10 is advanced by backloading main vessel guidewire 36 into main guidewire lumen 35 in catheter system 10, and branch vessel guidewire 38 into side sheath 30 and branch vessel guidewire lumen 40 in catheter system 10. The main guidewire 36 and the branch guidewire 38, after being so placed, are then used for tracking the catheter system 10 to its proper position before deploying the stent 32, as depicted in FIG. 6B.

In alternative embodiments, a single side dual guidewire lumen catheter system 100 is envisioned, wherein either a branch vessel guidewire lumen or a main vessel guidewire lumen has an exit port relatively close to a distal end of the catheter system, and wherein the other lumen extends proximally along the length of the catheter system. Such systems are described in co-pending U.S. Patent Application Serial Number 09/860,744, filed May 18, 2001, incorporated herein by reference in its entirety.

Several methods are suitable for advancing a single side dual guidewire lumen catheter system to a bifurcation. For a system with a long main vessel guidewire lumen and a short branch vessel guidewire lumen, a main vessel guidewire is preloaded into the main vessel guidewire lumen, and a branch vessel guidewire is inserted into the main vessel or the branch vessel. The entire system is then advanced over the branch vessel guidewire, until the catheter is just proximal to the bifurcation. If the branch vessel guidewire is in the branch vessel, the main vessel guidewire is advanced into the main vessel and the entire system is advanced over both wires until the stent is properly positioned. If the branch vessel guidewire is in the main vessel, the branch vessel guidewire is retracted and then advanced into the branch vessel, after

which the main vessel guidewire is advanced into the main vessel and the system is advanced over both wires.

For a system with a long branch vessel guidewire lumen and a short branch vessel guidewire lumen, a branch vessel guidewire is preloaded into the branch vessel guidewire lumen, and a main vessel guidewire is inserted into the main vessel. The entire system is then advanced over the main vessel guidewire, until the catheter is just proximal to the bifurcation. The branch vessel guidewire is then advanced into the branch vessel, and the system is advanced over both wires.

It is appreciated that certain features of the invention, which are, for clarity, described in the context of separate embodiments, may also be provided in combination in a single embodiment. Conversely, various features of the invention, which are, for brevity, described in the context of a single embodiment, may also be provided separately or in any suitable subcombination.

Although the invention has been described in conjunction with specific embodiments thereof, it is evident that many alternatives, modifications and variations will be apparent to those skilled in the art. For example, self-expanding stents may be used, wherein a balloon is not used. Accordingly, it is intended to embrace all such alternatives, modifications and variations that fall within the spirit and broad scope of the appended claims. All publications, patents and patent applications mentioned in this specification are herein incorporated in their entirety by reference into the specification, to the same extent as if each individual publication, patent or patent application was specifically and individually indicated to be incorporated herein by reference. In addition, citation or identification of any reference in this application shall not be construed as an admission that such reference is available as prior art to the present invention.